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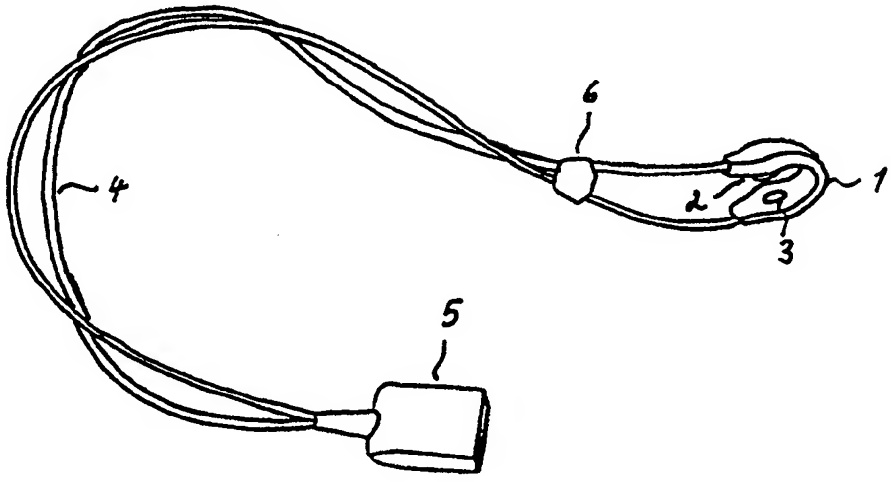
(57) Abstract

The invention relates to an oximeter probe which can be placed more freely and at more locations on the body than normal oximeter probes, because its ability to measure is retained at measurement distances which are longer than the conventional ones, irrespective of the skin pigment. The invention is characterised in that the probe comprises a transmitter section (2) which emits light in the wavelength range of 710 nm to 770 nm and of over 805 nm, a receiver (3), and a probe part (1) which is made of a flexible material fitting closely to its positioning place, for example silicone. Furthermore, in the probe according to the invention it is possible to place an auxiliary transmitter (9) immediately adjacent to the receiver (3) as a light source for a wavelength range below 600 nm, with which transmitter the plethysmographic pulse curve is measured. The invention relates further to a fastening mechanism for the probe where the cables (4) together with the probe part (1) and the securing component (6) form the fastening mechanism.



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Infrared oximeter fitting to its positioning place

The invention relates to an oximeter probe which is able to measure at measurement distances (which means the distance between the transmitter and the receiver) which are longer than normal, so that the ability to measure does not depend on the skin pigment. The probe comprises a receiver and a transmitter section, which emits two different wavelengths in the infrared range. The actual probe part is made of a flexible material, for instance silicone which fits closely to its positioning place. The invention further relates to a fastening method by which the probe can be attached to a patient.

Prior art level

Oximetry (means pulse oximetry) is employed in patient monitoring equipment for monitoring the heart rate and the oxygen saturation SaO_2 of the blood. The pulse oximetry method is based on a non-invasive optical measurement which monitors the absorption of two different wavelengths of light (red and infrared) in the tissue. Said method is common knowledge and there are several manufacturers of oximetry equipment. There are two main types of oximeters, a so called transillumination oximeter based on light passing through the tissue, and an oximeter based on light reflected from the tissue. In practice the principle is the same in both measurements, and normal oximeters are able to perform reasonably both measurements and their intermediate forms. An aim in the measurements is generally to use the transillumination principle, because then the obtained signal amplitude is about fivefold compared to that of the reflection principle.

Present oximeter probes

There are many models of the oximeter probes, because in different situations it will be necessary to attach the probe at different places on the body. The positioning place is determined by the patient's size, weight, pigment and blood flow

rate in the measurement location. Frequently used positioning places for adults and older children are the fingers, toes and in a special case the auricle, for babies again the outside edge of the foot or palm. In addition to the above mentioned positioning places there is an excellent surface blood circulation also at the forehead, cheeks and the top of the head, but otherwise these places are not suitable for attaching the probes. Even if a pulse signal can be weakly detected also at other parts of the body the oximeter devices with present-day probes are not in practice able to measure the oxygen saturation in other places than in areas with a dense capillary system.

Problems of present oximeter probes

Already the fact that oximetry requires a number of different probes could be regarded as a problem, but the real problem is that the measurement locations to be used are located at areas of peripheral blood circulation. Shock and chill will reduce the blood circulation just in these areas, particularly during long surgical operations chill is common. This makes it difficult and in the worst case even prevents the measurement at the fingers and the toes. For this problematic situation there was developed a probe which is placed on the auricle, because in the above mentioned situations the blood circulation in the auricle remains sufficient for the measurement a little longer than the blood circulation in the fingers and the toes. However, it is not preferable to use the auricle probe continuously, because in a prolonged use the pressure caused by the fastening mechanism (clothes peg fastening means) will interfere with the measurement. Further the auricle probe, as well as the finger probe, will come off very easily. Therefore the outer edge of the foot or the palm used for babies would be an excellent positioning place also for adults, but at normal measurement wavelengths the ability of red light to pass through the tissue is not sufficient, particularly concerning dark-skinned persons.

The objective of the invention

The objective of the oximeter probe according to the invention is to enable a freer location of the probe at more places on the body than possible with present-day oximeter probes, such as an oximeter measurement in an area of sparse dermal blood vessels. A further objective is to reduce the problems in oximeter measurements caused by skin pigment, to increase the reliability of the oximeter measurement, to facilitate a correct location of the probe also in the most demanding measurement locations (such as on the chest and on the arms and upper arms), and to increase both the comfort in the use of the probe and the reliability of the fastening mechanism.

The characteristics of the invention are presented in the claim 1.

General description of the probe according to the invention

The oximeter probe according to the invention comprises a probe part of a material which is flexible and closely fitting to its positioning place, whereby the probe part contains one or more transmitter sections which emit light at a wavelength range 710 to 770 nm and over 805 nm and one or more receivers. Further, in a probe according to the invention it is possible to locate an auxiliary transmitter immediately adjacent to the receiver/receivers, as a light source of a third wavelength range. The invention comprises also a fastening mechanism for the probe where the cables together with the probe part and the securing component form the fastening mechanism.

Below the invention is described in detail with reference to the enclosed figures.

Figure 1 shows absorption curves of oxyhemoglobin and reduced hemoglobin.

Figure 2 shows an oximeter probe according to the invention according to one solution.

Figure 3a shows an oximeter probe according to the invention attached to a finger, according to one alternative.

Figure 3b shows an oximeter probe according to the invention attached to the leg of a baby or a small child, according to the transillumination measurement variant. In this case the probe part can be larger than normally.

Figures 4a and 4b show the positioning place of an oximeter probe according to the invention at the palm and at the foot. Figure 4a further shows a possible way for positioning.

Figure 5 shows an oximeter probe according to the invention which is positioned on the body and on the upper arm. Also in these positioning places the size of the probe can be practically enlarged.

Figure 6a shows an oximeter probe according to the invention when it is straightened and seen from that side which is located against the skin.

Figure 6b shows the positioning place of the auxiliary transmitter connected to an oximeter probe according to the invention, according to one embodiment, in a model where also the number of the basic transmitters and receivers has been increased.

Figure 6c shows an oximeter probe according to the invention when it is straightened and seen from one side in a model where the transmitter and the receiver are bent towards each other.

Figure 7a shows an oximeter probe according to the invention which is equipped with a cable fastening mechanism.

Figure 7b shows an oximeter probe according to the invention which is equipped with a cable fastening mechanism which uses an interconnector part.

Figures 8a and 8b show an oximeter probe according to the invention attached to a finger in two different ways using the cable fastening according to figure 7a.

Figure 9 shows an oximeter probe according to the invention attached to the palm using the cable fastening mechanism according to figure 7b which is equipped with an interconnector part.

Figures 10a and 10b show from different angles the securing component of the cable fastening mechanism of the oximeter probe according to the invention shown in figure 7a.

Figures 11a and 11b show from different angles the interconnector part of the cable fastening mechanism of the oximeter probe according to the invention shown in figure 7b.

Problems in oximeter measurement

The diagram shown in figure 1 shows for different wavelengths the absorption curves of oxygen containing hemoglobin (oxyhemoglobin) and of oxygen lacking hemoglobin (reduced hemoglobin). Present-day oximetry uses as one measurement wavelength the red wavelength close to 660 nm and as the second wavelength, a wavelength close to 900 nm in the infrared range (805 nm to 940 nm) is generally chosen, whereby the choice partly depends on the employed LEDs. At the above mentioned wavelengths the aim has been to obtain the maximum relative difference between the absorption factors of oxyhemoglobin and reduced hemoglobin, whereby the measurement accuracy should also be the best possible. This theory has also been widely applied in practice, but the measure-

ment accuracy and measurement ability have not been at their best in all cases as the skin pigment causes problems, because it attenuates strongly the red light entering the tissue. At longer measurement distances (which means the distance between the transmitter and the receiver) there will also arise a problem in that the red light has a poorer ability to pass through the tissue. Furthermore, at low saturation readings (below 85 %) the inaccuracy of the measurement increases substantially (the percentage indicates the relative amount of oxygen bound in the hemoglobin, compared to the theoretical maximum bound amount which is normally about 97 %, except for a new-born and a fetus).

Furthermore, when the measurements are made at conventional wavelengths and when the measurement distance increases the signal-to-noise ratio will decrease due to the following reasons. The ability of 660 nm to pass through tissue is substantially lower than that of infrared light, so that the red light signal may become insufficient for the measurement. Also other interferences, such as problems caused by external light are emphasised in a situation where the signal strengths differ from each other. The visible light and the infrared light also have substantially differing scattering characteristics in the tissue, whereby the probe motion artefacts are more difficult to attenuate, because they appear with different magnitudes.

Advantages of an infrared oximeter

The advantages of an oximeter utilising only the infrared range emerge indisputably, particularly in situations where the patient has a pigment which is darker than usual, or in situations where the measurement distance must be radically increased, such as when the oxygen saturation is measured in an area with a sparse capillary system where the signal level at normal distances will be too low (the signal amplitude increases directly proportional to the distance which the light travels in the tissue). For instance in tests presented in the literature, measure-

ments based on the transillumination principle and made at normal wavelengths have been possible (depending on the tissue type and the pigment) at measurement distances up to about 15 to 25 mm, and in oximeters operating on the reflection principle the maximum measurement distance is 3 to 14 mm. By means of the improvements according to this invention the measurement distance can be increased in both cases to be over 40 mm, which enables i.a. a measurement through the upper arm or the leg of a small child or a baby.

Furthermore, the problem due the different scattering is substantially reduced if infrared light in the range of 700 to 780 nm is used instead of the red light in the oximeter measurements. Then the scattering and absorption of both wavelengths used in the measurement are very similar when they pass through bloodless tissue, and their absorptions differ from each other only in substances having importance regarding the actual measurement, in other words in oxyhemoglobin and reduced hemoglobin. Though the relative difference of the absorption factors of oxyhemoglobin and reduced hemoglobin in this case will be smaller than in an oximeter utilising conventional wavelengths, the above mentioned advantages will compensate for this fact reducing the theoretical measurement accuracy. Further the measurement accuracy at low saturation values is better, because for instance the US-patent 5421329 states that using a wavelength in the range of 700 nm to 790 nm instead of the red 660 nm it is possible to measure the oxygen saturation with a higher accuracy at SaO_2 values which are lower than normal. The device described in the above mentioned patent publication was designed to determine the oxygen saturation of the blood in a fetus during the pregnancy and the delivery (the normal oxygen saturation value of a fetus is about 80 %).

Due to the above mentioned facts the invention has arrived at the following solutions

The oximeter probe according to the invention (figure 2) comprises a transmitter

section 2 which can emit at least one wavelength in both wavelength ranges, which are 710 nm to 770 nm and 805 nm to 1000 nm, and a receiver 3, both located in the probe part 1. The probe part is made of a flexible material, for instance silicone, fitting closely to its positioning place. The probe part comprises also a cable 4 and a connector 5, with which the probe is connected to an intermediate cable or to a measurement instrument. The probe can be attached to the patient with a tape, with a self-adhesive patch, with a separate flexible wrap-around strip 8, or with the cable fastening system mentioned below.

Even though the use of different wavelengths of light in oximetry has been studied already since the nineteen forties and said probe model (a flexible silicone probe) as such is previously known, there is no mention in the literature or in publications that such a probe part would be used according to this invention. Furthermore, the method to connect an auxiliary transmitter 9 to the probe, which is described later, is not known previously, and neither is the probe fastening system shown in figures 7a and 7b. The measurement method presented in figure 3b is not either known previously. Also the measurement locations shown in figure 5 have in practice been impossible concerning people with a dark pigment.

Furthermore, as the light source of a third wavelength range (below 600 nm), an auxiliary transmitter 9 can be placed immediately adjacent to the receiver 3 (at a distance of 1 to 3 mm) or between two transmitters, as is shown in figures 6a and 6b. In this wavelength range the absorption of both hemoglobins rises steeply (figure 1), so even for a very short measurement distance it is possible to obtain an excellent plethysmographic pulse curve. Particularly the green light range has proved to be suitable for this purpose. This is of importance particularly when long measurement distances are used. For instance, when the measurement distance in a the reflection type measurement exceeds 6 mm the motion artefacts begin to increase. This is due to the fact that the transmitter and the receiver at a

long distance from each other do not anymore move in synchronism with the tissue to be measured. When the auxiliary transmitter is placed in the above mentioned manner next to the receiver the plethysmographic pulse curve can be detected even during a strong movement. This can be used also to improve the oximeter measurement by synchronising the sampling moments (of samples used for the SaO_2 calculation) on the basis of information obtained hereby. Furthermore, in the reflection type measurement the measurement performance of the oximeter probe can be further improved by inclining the transmitter and receiver towards each other, whereby the measurement will become partly transmissive.

Furthermore, the transmitter 2 and the receiver section 3 can be slightly raised upwards from the level of the probe bottom and/or bent towards each other. Then the scatter at the interfaces between the skin and the probe components can be minimised and the light can be better directed to the receivers. Further the probe side placed against the skin can be of a material reflecting light, whereby the light intensity will be less attenuated as the measurement distance increases. The lengths, widths and heights of the probe part and the cables can be in different proportions than shown in figures 6a, 6b, 6c, 7a and 7b. Further the number and locations of the probe components can vary. It also possible to place transmitter and receiver components at the centre of the probe part.

Fastening method

In the oximeter probe according to the invention it is also possible to use a cable fastening mechanism of the following kind, which is presented in figure 7a. The fastening mechanism contains cables 4 connected to both ends of the probe part 1, whereby the cables pass through the movable securing component 6 (figures 10a and 10b). The securing component is designed so that the different input and output angles from the securing component should cause as little variations as possible in the friction force between the cables and the securing component, so

that in positioning places of different thickness the tension of the probe can be kept as constant as possible. The securing component can also employ a locking mechanism, with which the movement of the securing component in relation to the cables can be prevented, when necessary. The probe cables can also be made resilient, whereby the probe is better kept in its place by following the motion of the positioning place. The cables are connected again to each other in the connector 5. The connector can also function as a safety release in situations where the pull in the cable causes danger to the patient. If the probe does not require the circuitry of the second cable it is possible to use the solution according to figure 7b where the interconnecting part 7 (figures 11a and 11b) join the cables. With this solution the securing component 6 can be freely placed in the desired place so that there will not be formed any loop in the cables. The probe part 1 can also be constructed so that it is pre-bent into the shape of a U and/or so that it tends to press lightly the transmitter 2 and the receiver 3 close to each other. When required, it is possible to use in the fastening means a double turn according to figures 8b and 9 around a limb. Thus the probe can be made to stay better in its place. The probe's fastening mechanism is also suitable for oximeters using other wavelengths, or for probes measuring other physical quantities. It is also possible, when required, to place several probes one after another, or the probe components can also be embedded in the cable itself, whereby no separate probe part is required.

The cable fastening mechanism according to the invention is well suited to most positioning places used in oximeter measurements, and further the positioning places shown in figure 4 can be used disregarding age and race. The measurement transilluminating the limb of a child or a baby as shown in figure 3b, and the positioning places on the upper arm and on the body shown in figure 5, were not possible positioning places previously (at conventional wavelengths), but a probe according to the invention can be located also there. Further the arms, the

thighs, the buttocks and the back are suitable positioning places.

Other measurements

In addition to the oximeter measurements also other measurements can be added to the probe, such as temperature, blood flow measurement based on laser or ultrasound doppler, skin humidity (electrical conductivity), EMG and blood pressure, whereby the cable in the cable fastening would also convey the pressure, and the fastening solution would act as a pressure belt. If the probe is attached to the body it is also possible to add an EKG measurement, as well as EEG if the probe is placed around the head. When required it is also possible to add to the probe other auxiliary transmitters for generating different wavelengths of light (required mainly for performing more accurate blood gas analyses, such as when determining the relative shares of other hemoglobins).

To a person skilled in the art is it obvious that the invention is not limited only to the above described example, but it may vary within the scope of the claims presented below.

Claims

1. An oximeter probe comprising a receiver section and a transmitter emitting two different wavelengths in the infrared range, **characterised** in that the probe comprises a transmitter section (2) which emits light in the wavelength range 710 nm to 770 nm and over 805 nm, a receiver (3), and a probe part (1) which is made of a flexible material fitting closely to its positioning place.

2. The probe according to claim 1, **characterised** in that that side of the probe part (1) which is placed against the skin is of a material which reflects light.

3. The probe according to claim 1 or 2, **characterised** in that it comprises an auxiliary transmitter (9) located immediately adjacent to the receiver/transmitters.

4. The probe according to claim 1, 2 or 3, **characterised** in that the transmitter (2) and the receiver section (3) are raised slightly above the bottom level of the probe.

5. The probe according to any of the claims 1 to 4, **characterised** in that the transmitter (2) and the receiver section (3) are bent towards each other.

6. The probe according to any of the claims 1 to 5, **characterised** in that it comprises a fastening mechanism where the cables (4) connected to each end of the probe part (1) together with the securing component (6) form the fastening mechanism.

7. The probe according to any of the claims 1 to 6, **characterised** in that the securing component (6) of the fastening mechanism contains a locking mechanism.

8. The probe according to any of the claims 1 to 7, **characterised** in that the cables (4) are flexible.

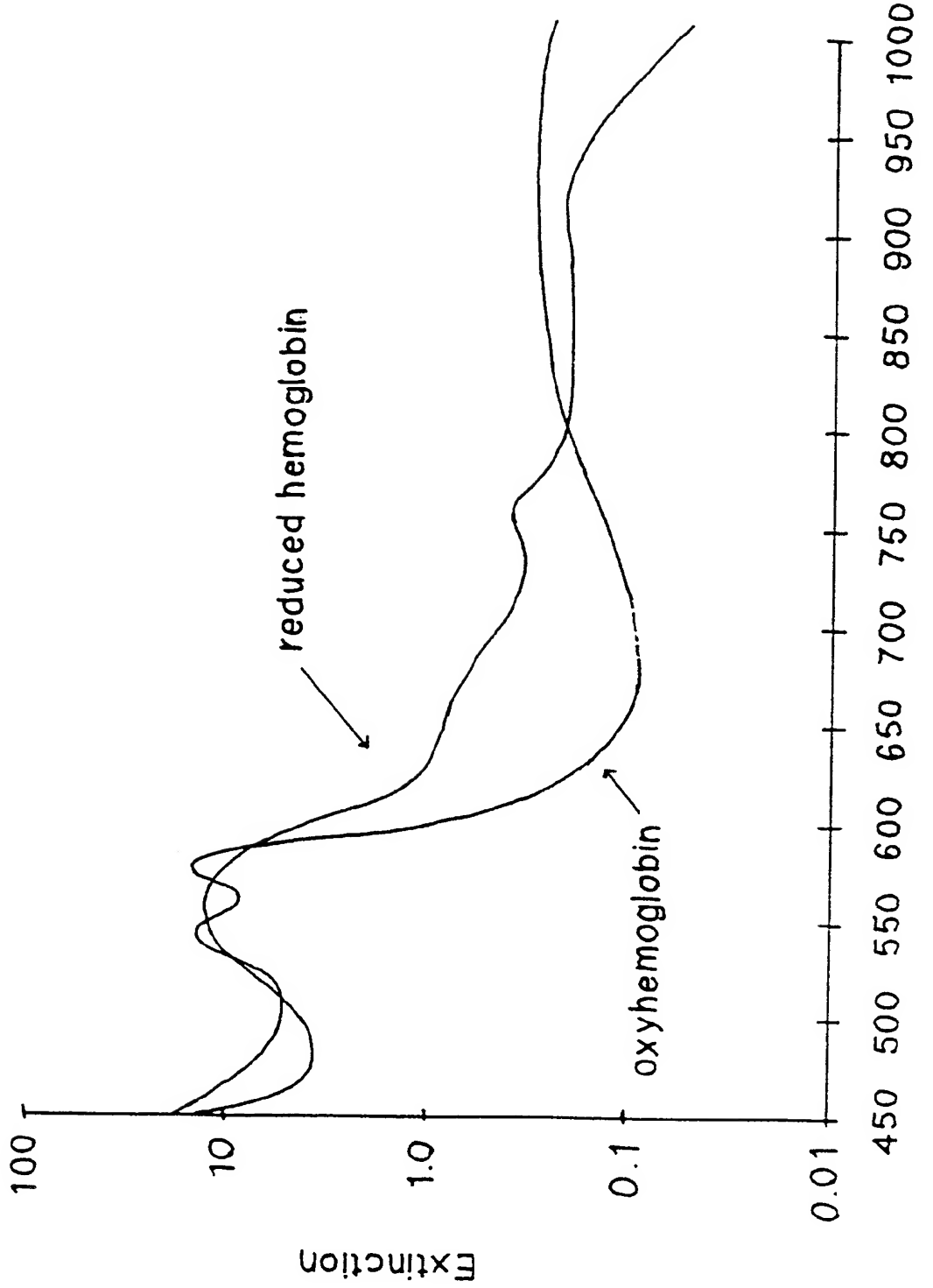
reduced hemoglobin
oxyhemoglobin
Extinction
100
10
1.0
0.1
0.01
450 500 550 600 650 700 750 800 850 900 950 1000
Wavelength (nm)

Fig. 1

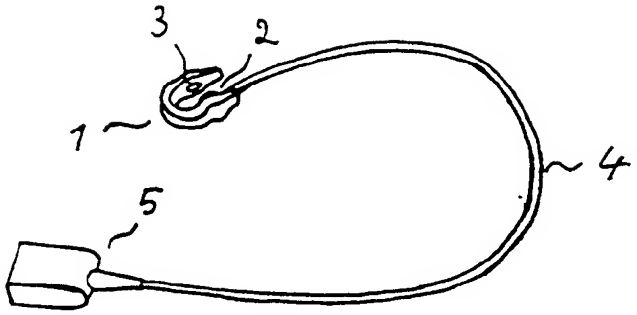

Fig. 2

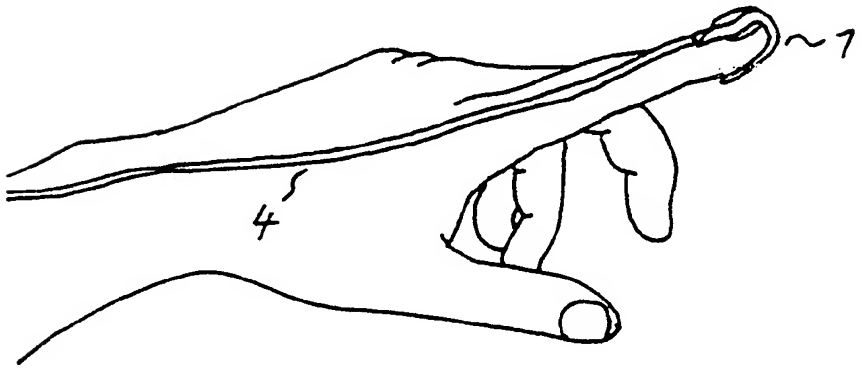

Fig. 3 A

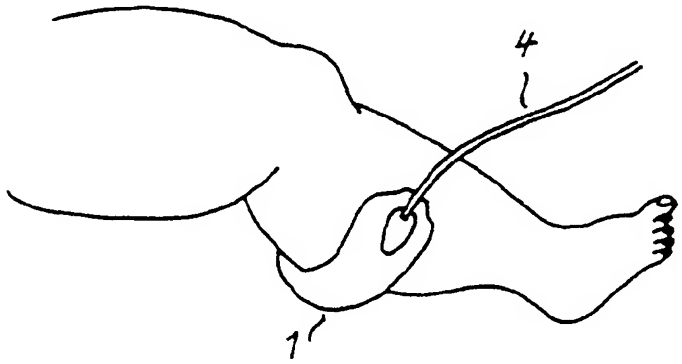

Fig. 3 B

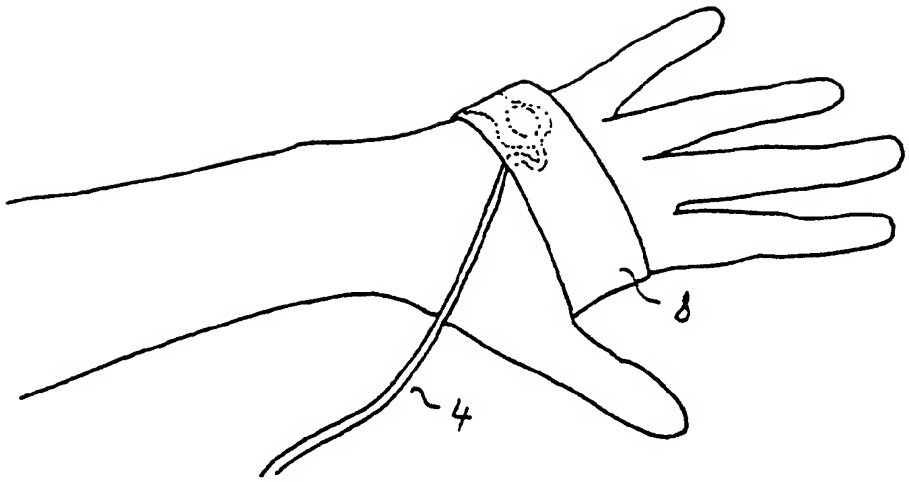

Fig. 4 A

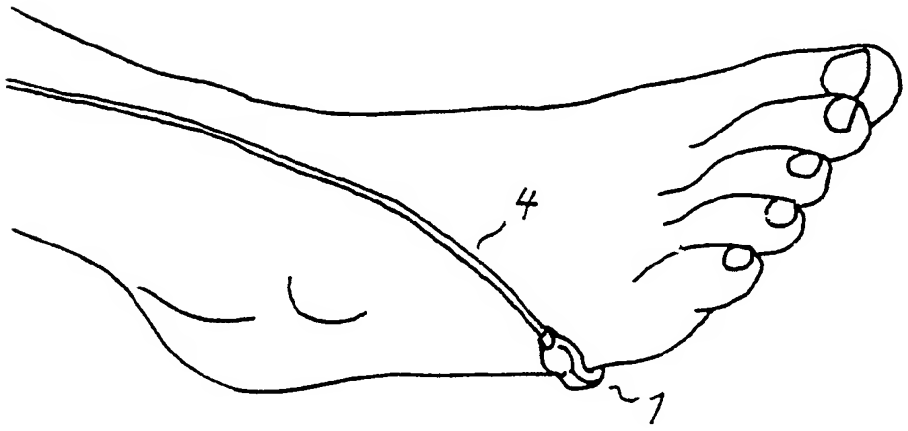

Fig. 4 B

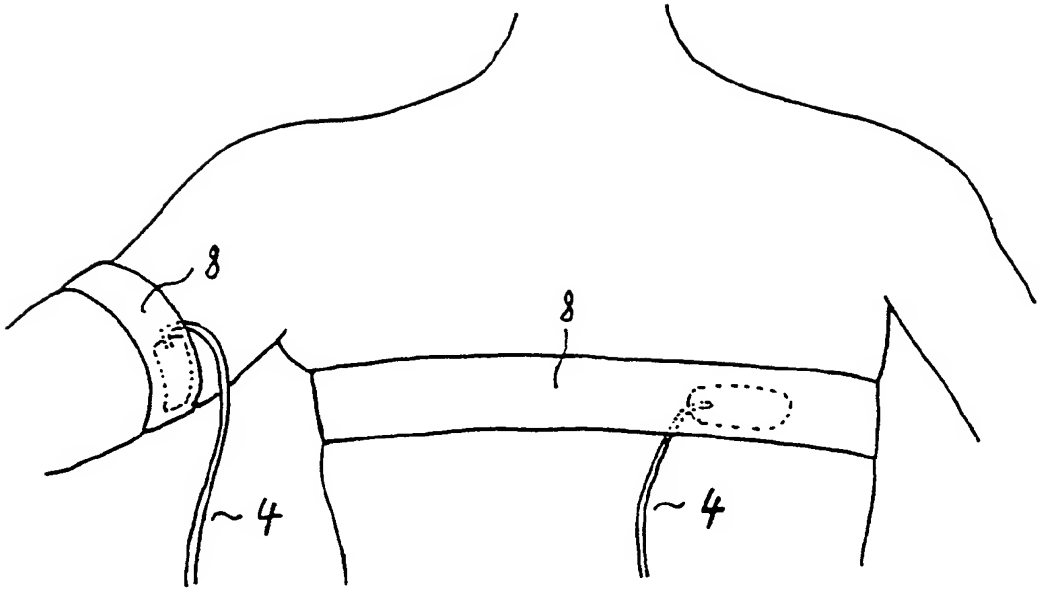

Fig. 5

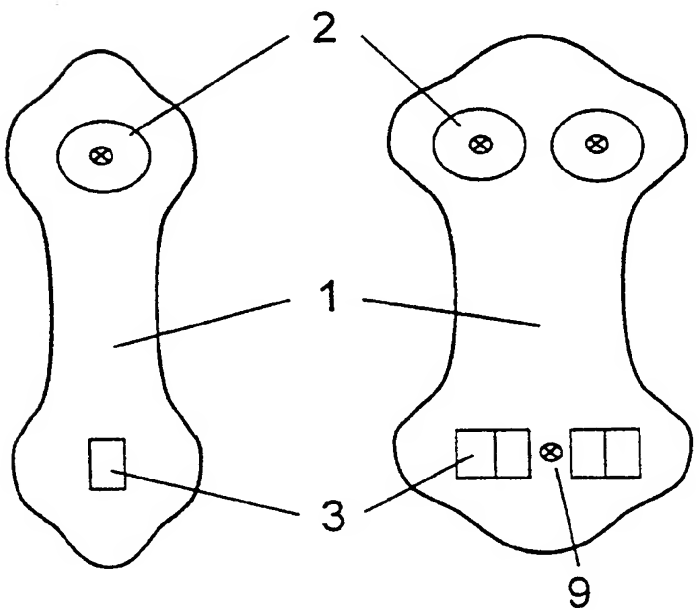

Fig. 6 A

Fig. 6 B

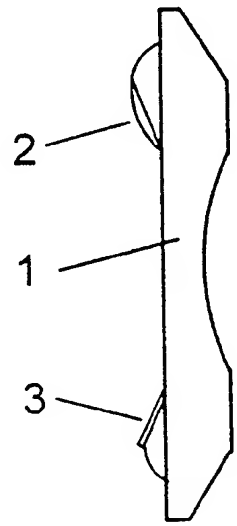

Fig. 6 C

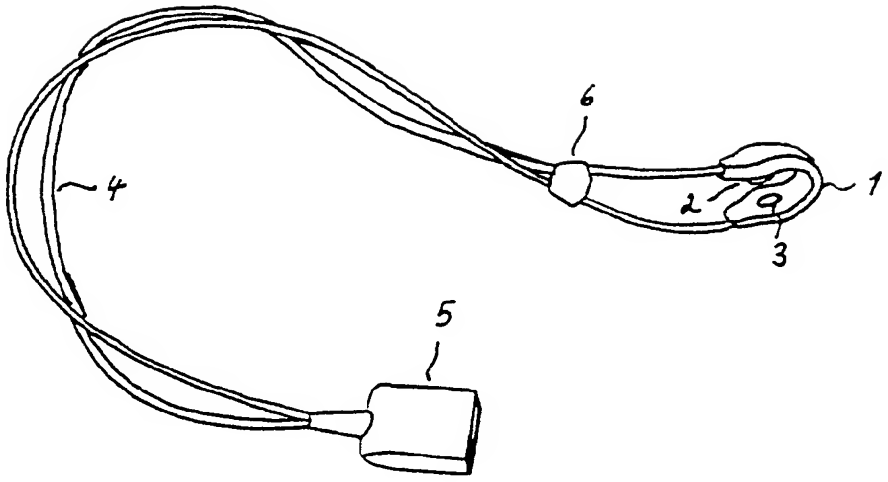

Fig. 7 A

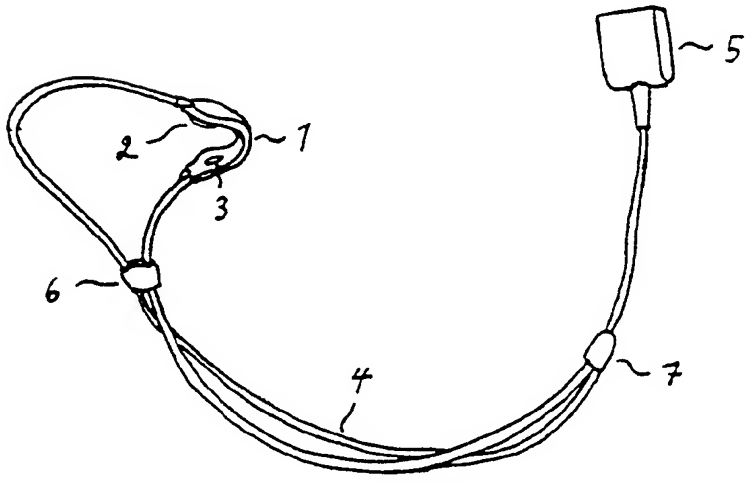

Fig. 7 B

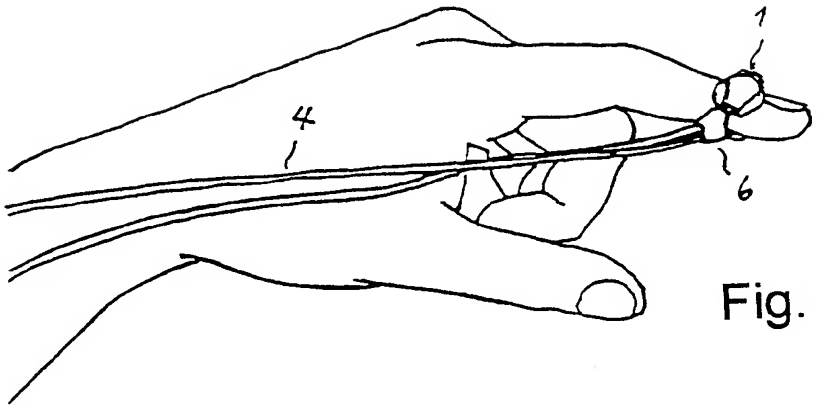

Fig. 8 A

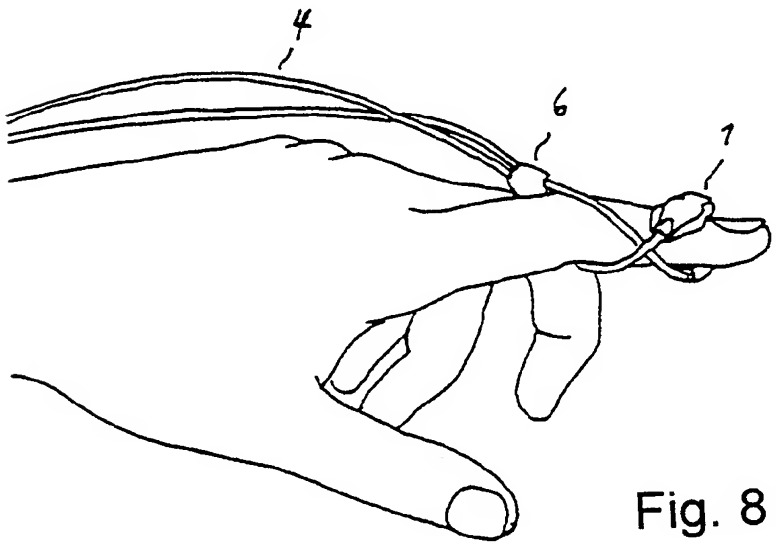

Fig. 8 B

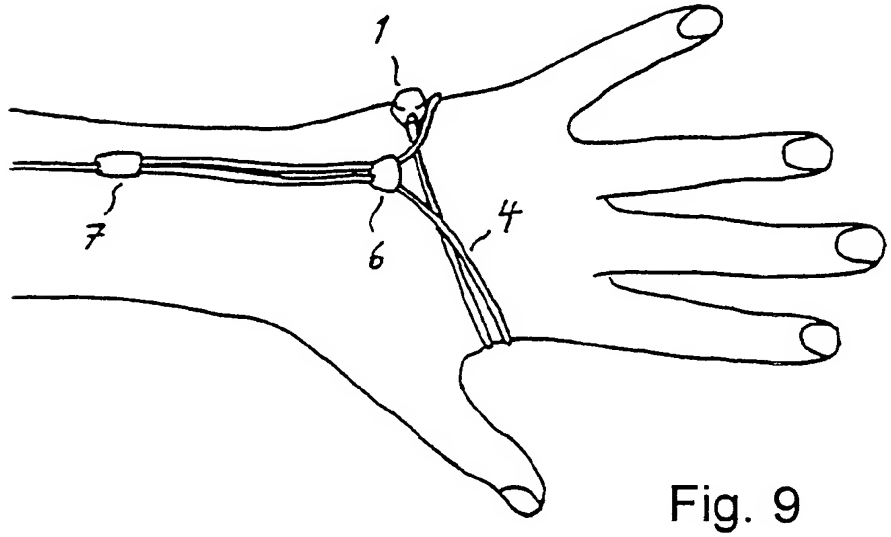

Fig. 9

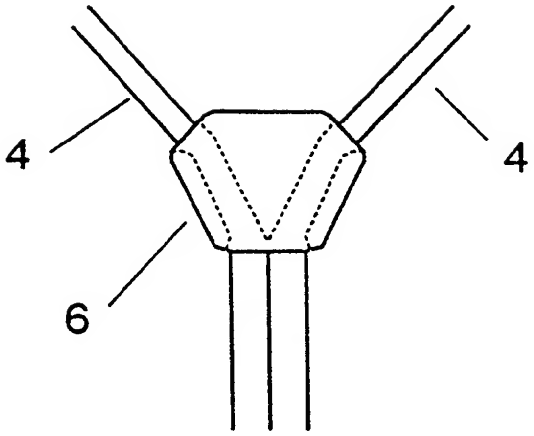

Fig. 10 A

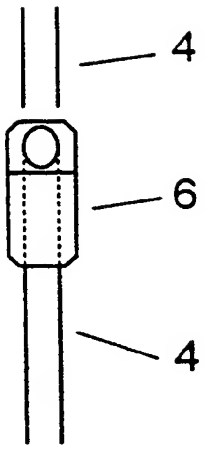

Fig. 10 B

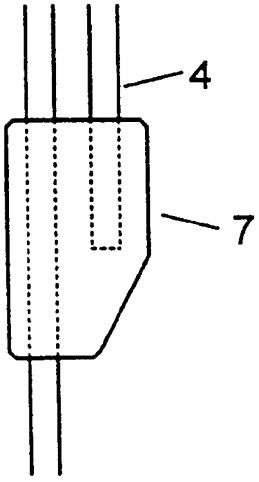

Fig. 11 A

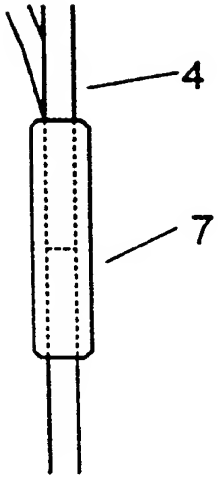

Fig. 11 B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 99/00193

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 5/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0572684 A1 (HEWLETT-PACKARD GMBH), 8 December 1993 (08.12.93), column 2, line 50 - column 3, line 35, figures 13,15 --	1-8
Y	US 5421329 A (J.R. CASCIANI ET AL.), 6 June 1995 (06.06.95), column 3, line 29 - line 37, figures 1, 3 --	1-8
A	WO 9805252 A1 (NELLCOR PURITAN BENNETT INCORPORATED), 12 February 1998 (12.02.98), figures 1,4, abstract --	1-8

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 July 1999	27 -07- 1999
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Patrik Blidefalk/AE Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 99/00193

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5709205 A (A. BUKTA), 20 January 1998 (20.01.98), figure 1, abstract -- --------	1-8

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/07/99

International application No.
PCT/FI 99/00193

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